This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

NOV 28 2005

See attached form for additional information.

Interagency Report Control No.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 22-R-0040
CUSTOMER NUMBER: 689

FORM APPROVED
OMB NO. 0579-0036

Huntingdon Life Sciences, Inc.
P.O. Box 2360
East Millstone, NJ 08875

Telephone: (732) -873-2550

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY **(Attach additional sheets if necessary or use APHIS Form 7023A)**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	686	100	27	813
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	0	159	10	2	171
9. Non-human Primates	100	268	110	18	396
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

(b)(6), (b)(7)(c)

DATE SIGNED 11/22/05

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

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A) Explanation of Category E Studies

All studies listed were conducted to conform to federally mandated requirements, promulgated by the US Food and Drug Administration (FDA). These regulations specify preclinical testing requirements necessary for approval of new drugs. Specific regulations include the following:

- 21 CFR 310, New Drugs
- 21 CFR 312.22, Investigational New Drugs/Biologics
- 21 CFR 314, Application for FDA Approval to Market a New Drug or Antibiotic Drug
- International Conference on Harmonization (ICH) Guideline M3 on Non-Clinical Safety Studies for the Conduct of Human Clinical Trials in Pharmaceuticals – Guidance for Industry, US Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), 1997
- International Conference on Harmonization (ICH) Guideline Topic S7, Safety Pharmacology, 2001.
- International Conference on Harmonization (ICH) Harmonized Tripartite Guideline (S5A): Detection of Toxicity to Reproduction for Medicinal Products, 1993.
- International Conference on Harmonization (ICH) S3A: Guideline on the Assessment of Systemic Exposure in Toxicity Studies, 1994.

Species	Number of Category E Animals	Description
Dogs	2	Animals were exposed to test compound via oral gavage. Test article effects were evident in two dogs. Consequently, these animals were humanely euthanized.
Dogs	10	Animals were exposed to test compound via capsule for one year. Test article effects were evident in 10 dogs. Consequently, these animals were humanely euthanized.
Dogs	1	Animals were exposed to test compound via intravenous administration. Test article effects were evident in one dog. Consequently, these animal was humanely euthanized.
Dogs	1	Animals were exposed to test compound via intravenous administration intermittently for approximately two weeks. Test article effects were evident in one animal. These brief effects resolved spontaneously.
Dogs	8	Animals were exposed to test compound via capsule administration intermittently for approximately two weeks. Test article effects were evident in 8 dogs. These brief effects resolved spontaneously.

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Species	Number of Category E Animals	Description
Dogs	4	Animals were exposed to test compound via oral gavage for approximately two weeks. Test article effects were evident in four animals. Consequently, these animals were humanely euthanized.
Dogs	1	Animals were exposed to test compound via intravenous administration. Test article effects were evident in one dog. Consequently, this animal was humanely euthanized.
Cyno	6	Animals were exposed to test compound via nasogastric intubation for approximately 14 days. Test article effects were evident in 6 animals. Consequently, dose was discontinued for one of these animals, and the remaining 5 of these animals were humanely euthanized.
Cyno	5	Animals were exposed to test compound via intravenous injection, for two separate 5-day cycles over an approximate 3-week period. Test article effects were evident in 5 animals. Consequently, these animals were humanely euthanized.
Cyno	4	Animals were exposed to test compound via intravenous infusion for a single dose. Test article effects were evident in 4 animals. Consequently, these animals were humanely euthanized.
Cyno	3	Animals were exposed to test compound via intravenous injection intermittently for approximately 2 weeks. Test article effects were evident in 3 animals. Consequently, these animals were humanely euthanized.
Rabbit	2	Animals were exposed to test compound via intravenous injection for approximately 2 weeks. Test article effects were evident in 2 animals. Consequently, dose was discontinued for one of these animals, and the remaining 1 these animals was humanely euthanized.

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B) Summary of IACUC-approved exceptions to the Standards and Regulations, by study:

- 3 dogs were exempted from the exercise requirement for 14 days during surgical recovery for implantation of a bile collection port.
- 46 dogs were exempted from the exercise requirement for 14 days during surgical recovery for implantation of a subcutaneous telemetry implant or bile collection port.
- 1 dog was exempted from the exercise requirement for 9 days due to test article effects.
- 9 dogs were exempted from the exercise requirement for 12 total days due to data collection via port(s).
- 12 dogs were exempted from the exercise requirement for a total of 24 days (10 days during surgical recovery, and 14 days for individual cardiovascular telemetry data collection).
- 16 dogs were exempted from the exercise requirement for 10 days during individual cardiovascular telemetry data collection.
- 8 dogs were exempted from the exercise requirement for 6 days during individual cardiovascular telemetry data collection.
- 10 dogs were exempted from the exercise requirement for 6 days during individual cardiovascular telemetry data collection.
- 4 dogs were exempted from the exercise requirement for 6 days during individual cardiovascular telemetry data collection.